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(71) Applicant: BIOENTERICS CORPORATION
[US/US]; 1035 Cindy Lane, Carpinteria, CA 93013 (US).

(72) Inventor: BIRK, Janel; 1110 Nightingale Place, Oxnard, CA 93030 (US).

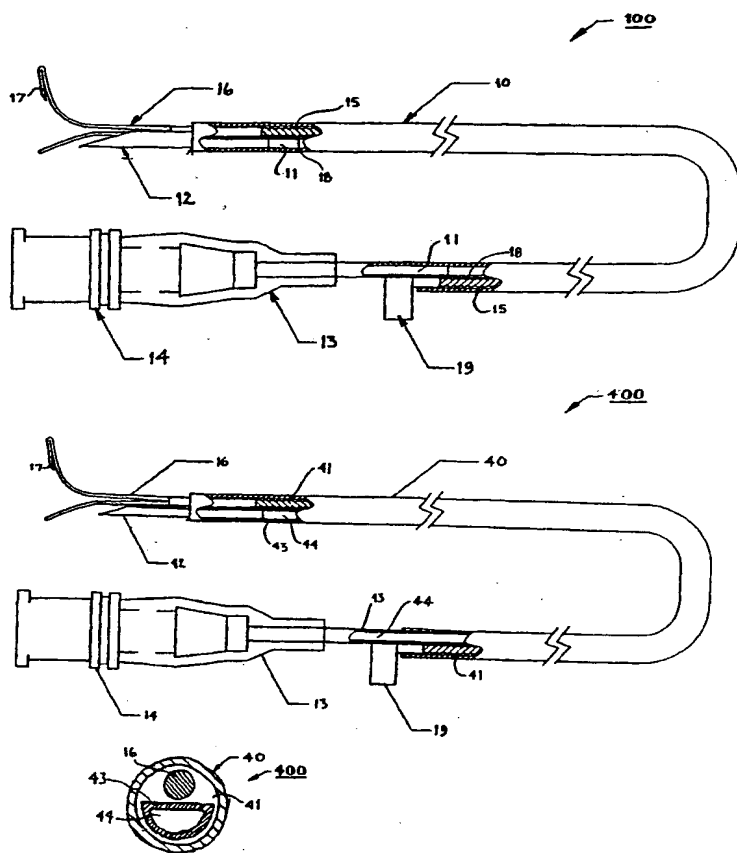
(74) Agent: VAN BUSKIRK, Tedd, W.; Milbank, Tweed, Hadley & McCloy LLP, 1 Chase Manhattan Plaza, New York, NY 10005-1413 (US).

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(54) Title: ENDOSCOPIC DEVICE FOR REMOVING AN INTRAGASTRIC BALLOON



(57) Abstract: A device and method for removing a fluid-filled object from a body cavity of a patient is provided. The device includes a tube and a grasper slidably movable with respect to the tube. The device also includes a needle fixed to one end of the tube. In use, the device is inserted into the body cavity, and the object is punctured with the needle. The object is grasped by the grasper, and the object and the device are removed from the body cavity.

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ENDOSCOPIC DEVICE FOR REMOVING AN INTRAGASTRIC BALLOON

BACKGROUND

1. Field of the Invention

The present invention relates to endoscopic devices for removing an intragastric fluid-filled object from the stomach of a patient.

5 2. Description of the Related Art

Intragastric balloons, such as that described in U.S. Patent No. 5,084,061, or commercially available as the BioEnterics Intragastric Balloon System (sold under the trademark BIB), are designed to provide short-term therapy for moderately obese individuals who need to shed pounds in preparation for surgery, or as part of a dietary and behavioral modification program.

The BIB system, for example, consists of a silicone elastomer intragastric balloon which is inserted into the stomach and filled with fluid. Commercially available intragastric balloons are filled with saline solution or air. The intragastric balloon functions by filling the stomach and enhancing appetite control. Placement of the intragastric balloon is non-surgical, usually requiring no more than 20-30 minutes. The procedure is performed endoscopically in an outpatient setting, using local anesthesia and sedation. Placement is temporary, and intragastric balloons are typically removed after six to twelve months.

Historically, endoscopic deflation and extraction of intragastric balloons has been an arduous task due to the difficulty associated with manipulating the balloon within the stomach. Due to the balloon's flexible nature, when pressure is applied to its surface for puncture, the shell will either elastically deform or the entire balloon will push away from the applied force.

The prior art method of removing the balloon involves several steps, each with its own tool. A sharp-ended puncture device, sometimes called a "killer," is inserted through the working channel of an endoscope to puncture the balloon. The puncture device is removed, and the saline
5 solution is either allowed to enter the stomach cavity, or removed via a tube inserted through the working channel and into the balloon. Finally, a grasping device or "grasper" having prongs, teeth, or a wire loop is inserted through the working channel to snag or snare the balloon and is used to pull the balloon through the esophagus or the working channel. Heretofore,
10 there has been no single instrument capable of being inserted down the working channel of a endoscope which will (1) pierce the balloon, (2) evacuate the fluid and deflate the balloon, (3) grasp the balloon, and (4) allow the deflated balloon to be withdrawn.

Therefore, it is desirable to provide an endoscopic device for removing
15 an intragastric balloon in which the above mentioned disadvantages are substantially overcome.

SUMMARY OF THE INVENTION

A device and method for evacuating and removing a fluid-filled object from a body cavity of a patient is provided. The device includes a tube and a
20 grasper slidably movable with respect to the tube. The device also includes a needle fixed to one end of the tube.

In use, the device is inserted into the body cavity, and the object is punctured with the needle. The object is grasped by the grasper, and the object and the device are removed from the body cavity.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic view which illustrates a crescent-form embodiment of the invention.

FIG. 2 is a longitudinal cross-sectional view of a crescent-form tube
5 embodying aspects of the invention.

FIGS 3A and 3B are, respectively, longitudinal and lateral cross-sectional views of a crescent-form cannulated needle embodying aspects of the invention.

FIG. 4 is a schematic view which illustrates a D-form embodiment of
10 the invention.

FIG. 5 is a longitudinal cross-sectional view of a D-form tube embodying aspects of the invention.

FIGS. 6A and 6B are, respectively, longitudinal cross-sectional and lateral views of a D-form cannulated needle embodying aspects of the
15 invention.

FIGS. 7A and 7B are, respectively, longitudinal and lateral views of a wire grasper embodying aspects of the invention.

FIGS. 8A and 8B are, respectively, longitudinal cross-sectional and schematic views which illustrate a nested-tube embodiment of the invention
20 having a dual-lumen outer tube.

FIGS. 9A and 9B are, respectively, longitudinal cross-sectional and schematic views which illustrate a nested-tube embodiment of the invention having a single-lumen outer tube.

DETAILED DESCRIPTION OF THE DRAWINGS

25 FIGS. 1-9 depict embodiments of the invention, each of which is a single device that can puncture the balloon, grasp the balloon, evacuate the

saline solution, and extract the device through the esophagus. FIGS. 1-6 depict a device **100, 200** constructed of dual lumen tubing **10, 20** that is small enough to pass through the working channel of an endoscope or gastroscope (not shown). One lumen **11, 21** has a cannulated needle **12, 22** fluidly coupled at one end of lumen **11, 21** for puncturing and suctioning out the saline solution. The other end of lumen **11, 21** is fluidly coupled by tubing **13** to luer connector **14** for connection to suction in the operating room or clinical office. The other lumen **15, 25** houses a grasper **16, 26**, having prongs **17**, which is free to slide within lumen **15, 25**.

When the balloon (not shown) full of fluid is ready for removal, the device **100, 200** is guided down the working channel (not shown) of an endoscope or gastroscope (not shown). The needle **12, 22** will be used to puncture and steady the balloon while the grasper **16, 26** is used to grasp the taut shell of the balloon. After the grasper **16** has grasped the balloon by snagging the balloon with the prongs **17**, the grasper **16** is retracted into the lumen **15, 25** to maintain a firm grasp of the balloon. Suction will then be applied to the luer connector **14** and thus to lumen **11, 21** and needle **12, 22** to evacuate the fluid. After all of the fluid is evacuated from the balloon, the entire device **100, 200** with the balloon attached is pulled up through the esophagus. It is anticipated that this mechanism will introduce ease of use, reliability, and could be produced at a reasonably low cost.

FIGS. 1, 2, 3A, 3B, and 4 depict aspects of a crescent-form embodiment of the device **100**, which is a preferred embodiment of the invention. FIGS. 4, 5, 6A, 6B, and 7 depict aspects of a D-form embodiment of the device **200**, which is another preferred embodiment of the invention.

The purpose for these two variations is to maximize the cross-sectional area of one lumen in the dual-lumen tubing.

In the crescent-form variation of the device **100**, tubing **10** has a lumen **11** having a crescent-shaped cross-section, which occupies the portion of tubing **10** not occupied by either lumen **15**, having a circular cross-section, or separating wall **18**. In this embodiment, needle **12** has a crescent-shaped cross-section for fluid-tight insertion into lumen **11**.

Similarly, in the D-form device **200**, tubing **20** has a lumen **21** having a D-shaped cross-section, which occupies the portion of tubing **20** not occupied by either lumen **25**, having a circular cross-section, or separating wall **28**. In this embodiment, needle **22** has a D-shaped cross-section for fluid tight insertion into lumen **21**.

In preferred embodiment of the invention, tubing **10**, **20** may be fabricated from PTFE, ETFE, or PDVF, and may have a 0.100" (2.540 mm) outer diameter; circular lumen **15**, **25** may have a 0.038" (0.965 mm) interior diameter. Needle **12**, **22** preferably has the form shown in either FIGS. 3A, 3B or 6A, 6B, and preferably is fabricated from 304 stainless steel, and may be fixed in place within lumen **11**, **21** using LOCTITE® 3201 UV cure adhesive. FIGS. 7A, 7B show a preferred embodiment of the grasper **16** of the invention, which is formed of three strands of .012" (3.048 mm) diameter 304 stainless steel wire **31** joined by solder connection **32**. Grasper **16** preferably has a handle **19** for manipulation by the operator.

FIGS. 8 and 9 depict nested-tube embodiments of the invention. The device **300**, **400** is constructed of an outer tube **30**, **40** that is small enough to pass through the working channel of an endoscope or gastroscope (not shown). An inner tube **33**, **43** and cannulated needle **32**, **42** are fluidly

coupled and are slidably movable within a lumen **31, 41** of outer tube **30, 40**. Lumen **34, 44** of inner tube **33, 43** is also fluidly coupled to luer connector **14**. Outer tube **30, 40** also houses a grasper **16** which is free to slide within lumen **35, 45** of outer tube **30, 40**. In these embodiments, 5 cannulated needle **32, 42** may be completely retracted within outer tube **30, 40** to prevent injury to the patient's esophagus or the working channel of the endoscope when the device **300, 400** is removed.

FIGS. 8A and 8B show a nested-tube embodiment as described above where dual-lumen outer tube **30** has a lumen **31** having a D-shaped cross-section, which occupies the portion of tube **30** not occupied by either lumen **35, 10** having circular cross-section, or separating wall **38**. In this embodiment, cannulated needle **32** and inner tube **33** have a D-shaped cross-section with dimensions appropriate to allow sliding movement within outer tube lumen **31**. By contrast FIGS. 9A and 9B show a nested-tube embodiment where outer tube 15 **40** has a single lumen **41**, in which both inner tube **43**, having D-shaped cross section, and grasper **16** are slidably movable.

In another embodiment of the invention, grasper **16** may have teeth rather than prongs, or may be a loop or snare. A longer or smaller number of prongs may be used than the embodiments illustrated in FIGS. 1-9.

20 In further embodiments of the invention, the cannulated needle may have circular or other cross sections.

In still further embodiments of the invention, a cannulated needle may be fluidly coupled to a single-lumen tube, inside which a grasper is slidably movable. In use, the punctured and evacuated balloon is grasped 25 and pulled into the cannulated needle.

It is to be understood that the above-described embodiments are merely illustrative of the principles of the invention and that other arrangements may be devised by those skilled in the art without departing from the spirit and scope of the invention.

I claim:

1. A device for removing an object from a body cavity of a patient comprising:
 - a first tube;
 - 5 a grasper slidably movable with respect to said first tube; and
 - a needle fixed to an end of said first tube.
2. The device of claim 1 wherein said first tube has a first lumen and a second lumen, said grasper slidably movable in said first lumen.
3. The device of claim 1 wherein said device has an outer diameter
10 suitable for insertion within a working channel of an endoscope.
4. The device of claim 1 wherein said needle is cannulated and fluidly coupled to said end of said first tube.
5. The device of claim 4 wherein said first tube has a first lumen and a second lumen, said needle fluidly coupled to said second lumen.
- 15 6. The device of claim 1 wherein said grasper has an end having at least one prong.
7. The device of claim 1 further comprising a second tube, said first tube slidably movable in said second tube and said grasper slidably movable in said second tube.
- 20 8. The device of claim 7 wherein said second tube has a first lumen and a second lumen, said grasper slidably movable in said first lumen and said first tube slidably movable in said second lumen.
9. The device of claim 7 wherein said grasper is slidably movable in a lumen of said first tube.
- 25 10. A method for evacuating and removing a fluid-filled object from a body cavity of a patient comprising the steps of: inserting a device

into the body cavity, said device having a first tube, a grasper slidably movable with respect to said first tube, and a needle fixed to a distal end of said tube;

puncturing the object with said needle; grasping the object with said grasper; and removing the object and said device from the body cavity.

11. The method of claim 10 wherein said needle is cannulated and fluidly coupled to said distal end of said first tube, and further comprising the step of evacuating at least some fluid from the object through said needle and said first tube.

12. The method of claim 11 further comprising the step of applying suction to a proximal end of said first tube so that fluid is evacuated from the object by said suction through said distal end of said first tube.

13. The method of claim 10, said first tube further having a first lumen and a second lumen, said grasper slidably movable in said first lumen and said needle is cannulated and fluidly coupled to said second lumen.

15. The method of claim 10 wherein said grasping step further comprises the steps of: extending said grasper from a distal end of said device; and retracting said grasper into said distal end of said device.

16. The method of claim 14 wherein said extending step further comprises extending said grasper from a first lumen of said first tube and said retracting step further comprises retracting said grasper into said first lumen of said first tube.

17. The method of claim 15 wherein said needle is cannulated and fluidly coupled to said distal end of said first tube, said extending step further comprises extending said grasper from said needle, and said

retracting step further comprising retracting said grasper into said needle.

18. The method of claim 10 further comprising the steps of: inserting said device into the working channel of an endoscope; and removing the object
5 and said device from said endoscope.

18. The method of claim 10 further comprising the steps of: inserting an endoscope into the body cavity; and removing said endoscope from the body cavity.

19. The method of claim 10 wherein: said grasper has an end having at
10 least one prong, and said grasping step further comprises snagging the object with said at least one prong.

20. The method of claim 10 wherein said device further comprises a second tube, said first tube slidably movable in said second tube and said grasper slidably movable in said second tube, and further comprising the
15 step of retracting said needle and said first tube within said second tube.

100

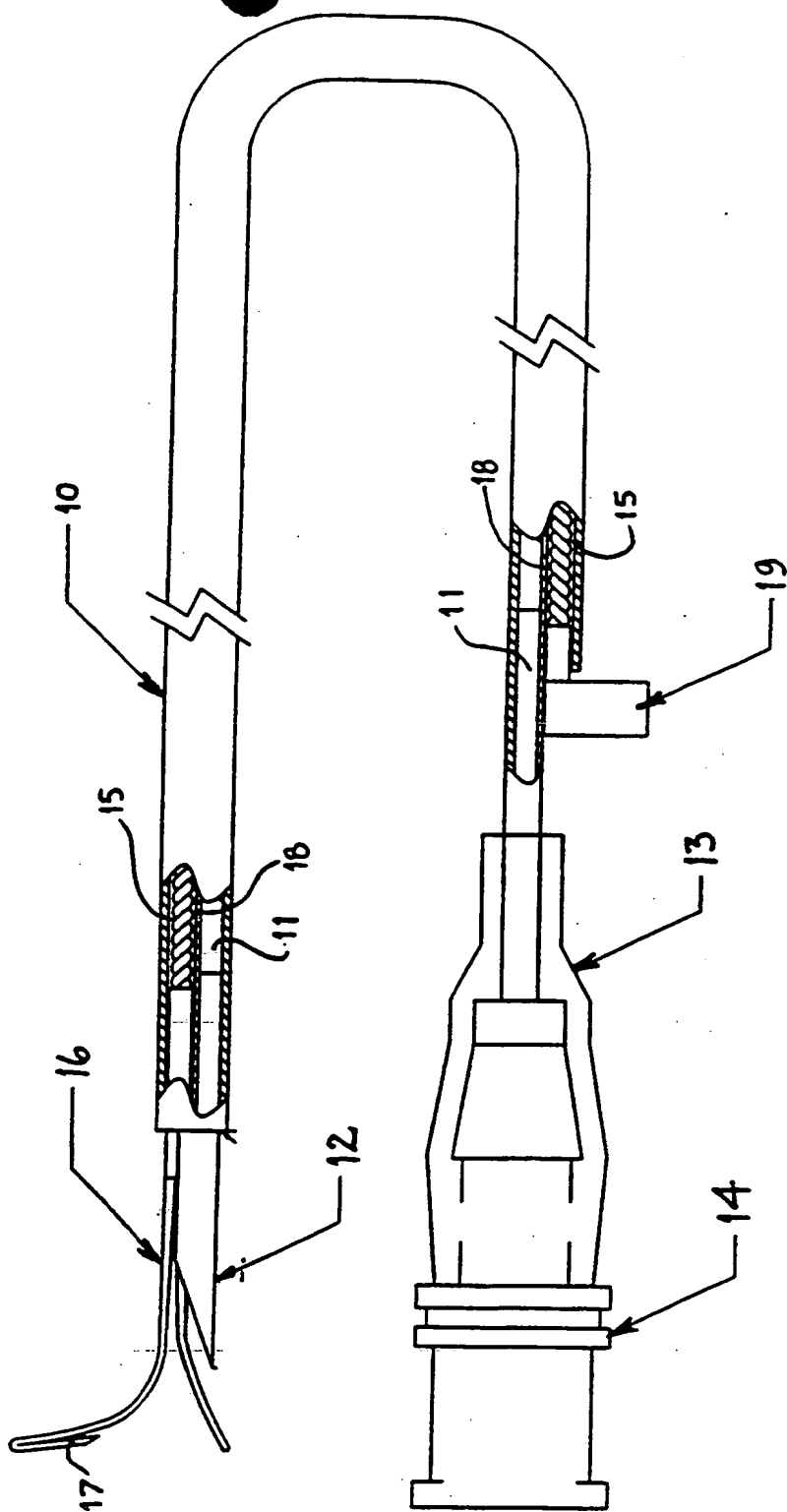


Fig. 1

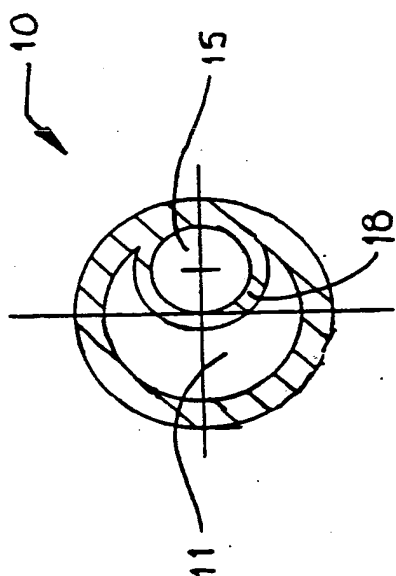


Fig. 2

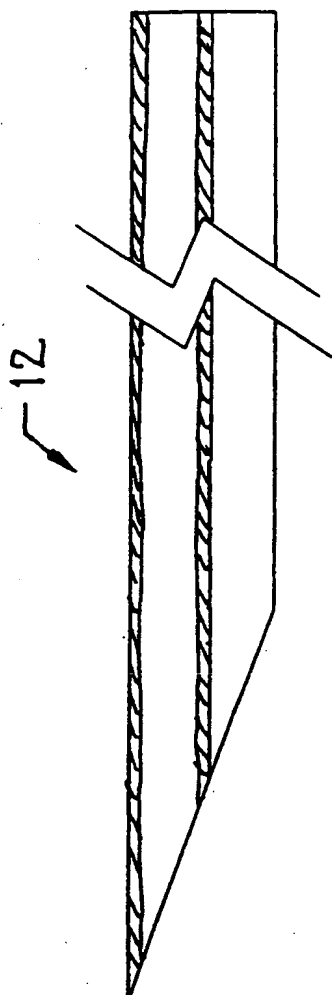


Fig. 3B

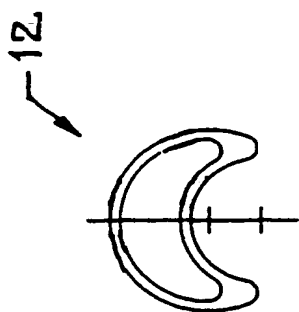


Fig. 3A

200

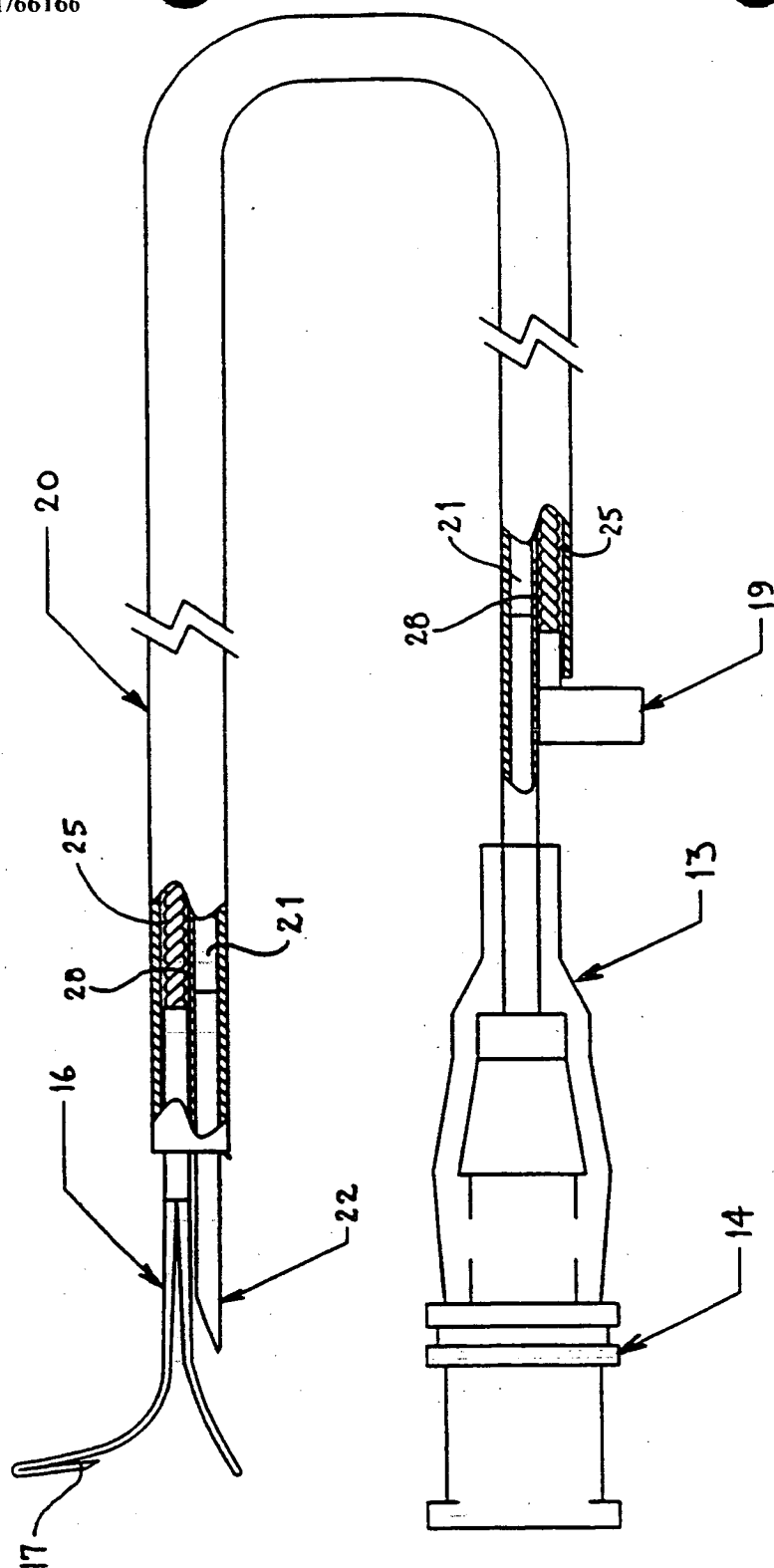


Fig. 4

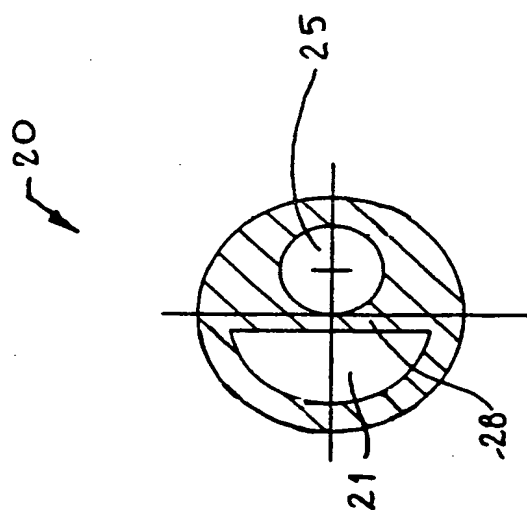


Fig. 5

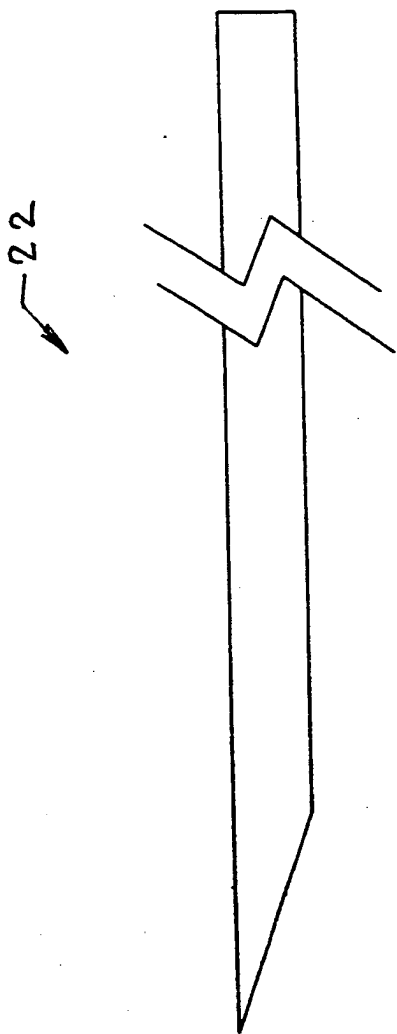


Fig. 6B

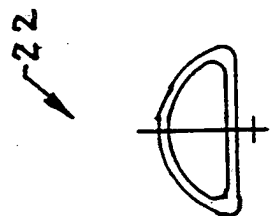


Fig. 6A

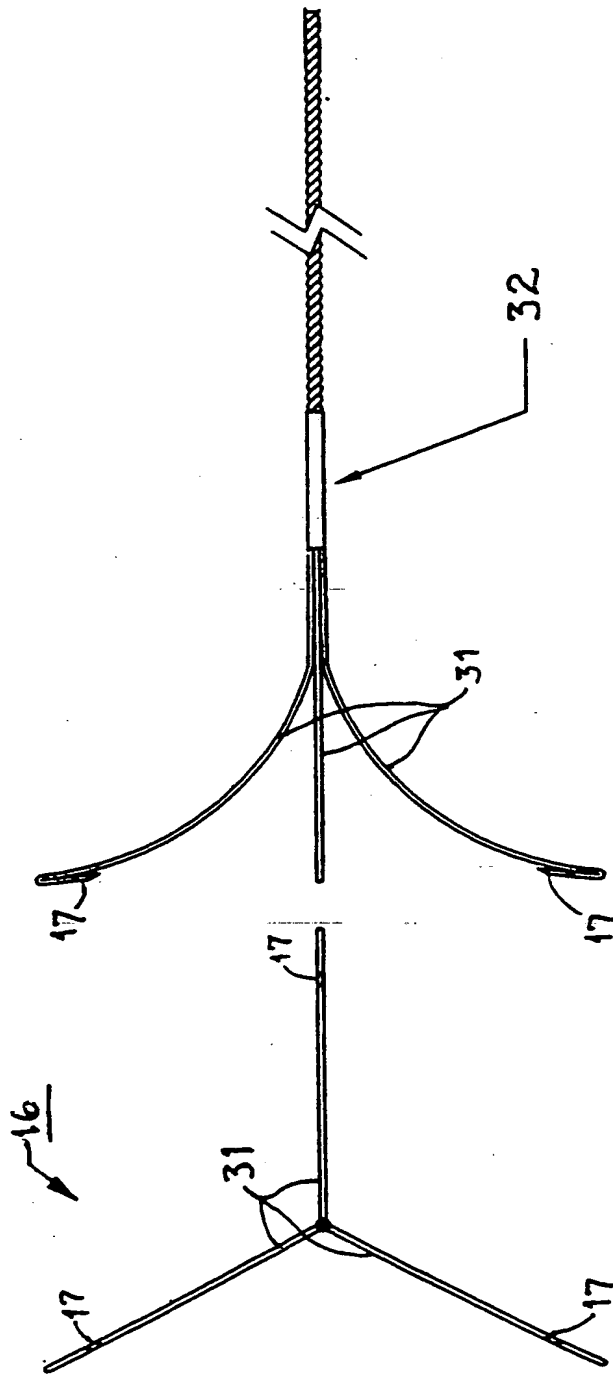


Fig. 7B

Fig. 7A

300

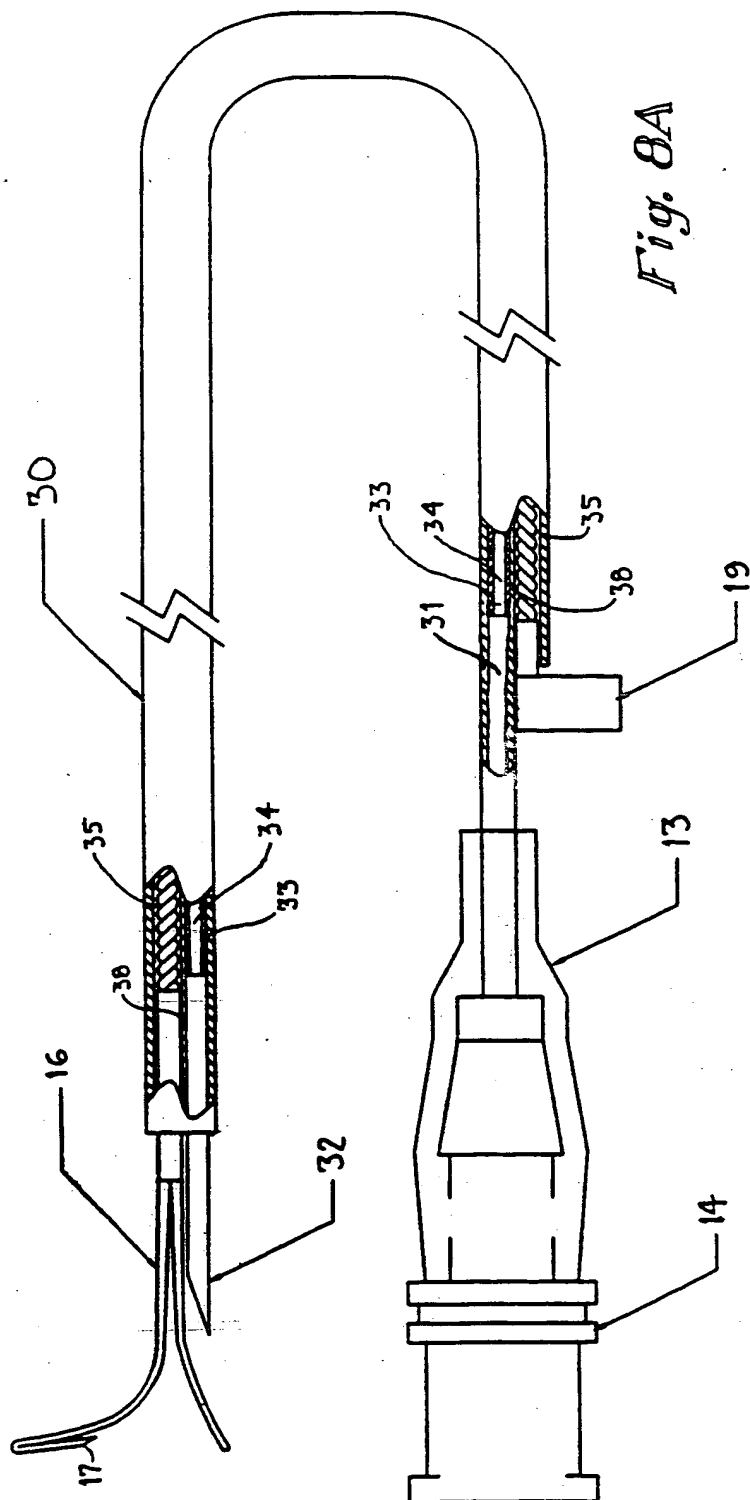


Fig. 8A

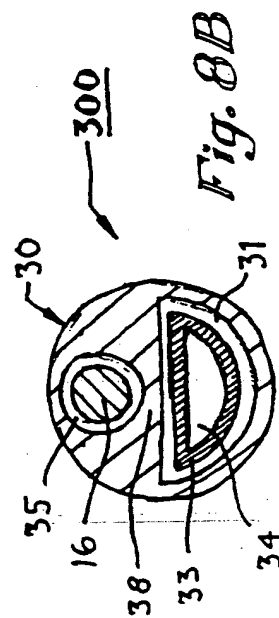


Fig. 8B

400

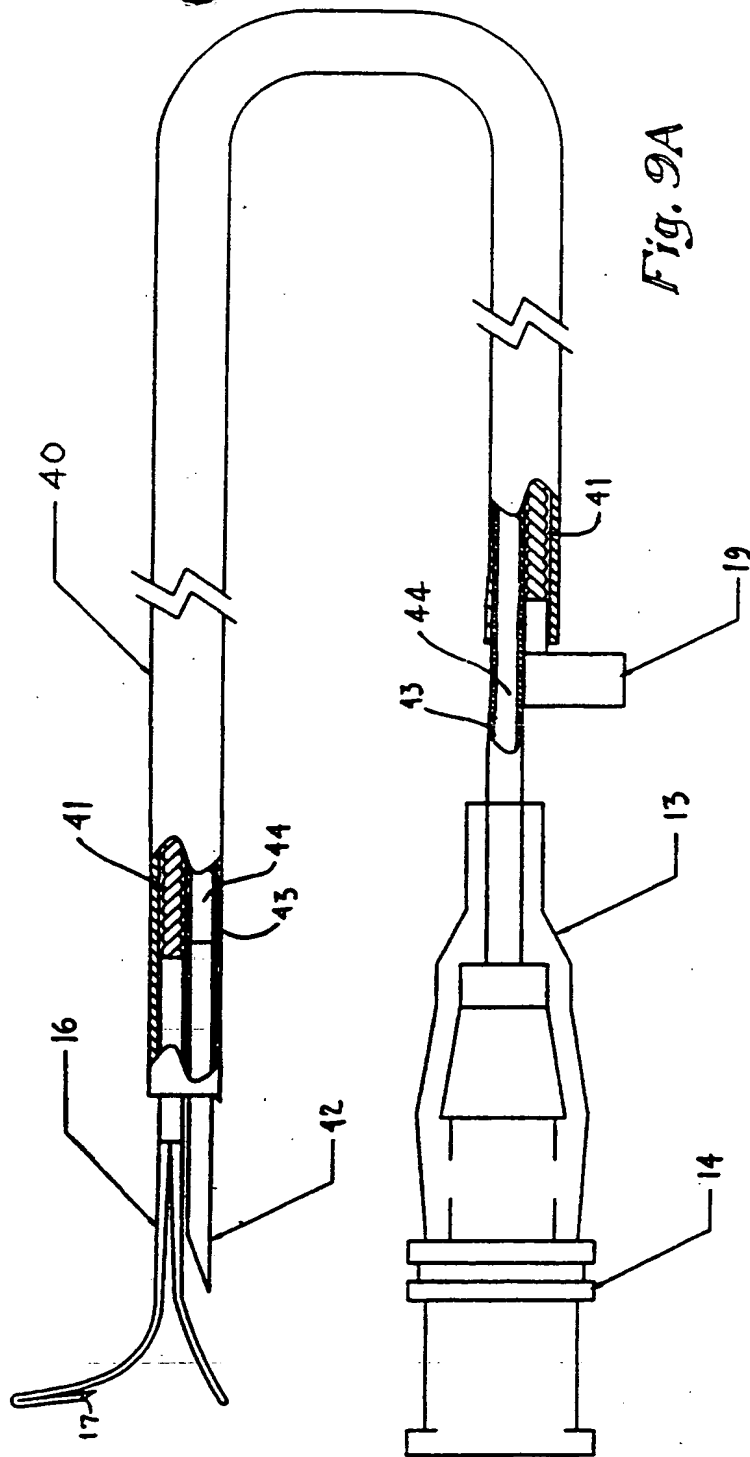


Fig. 9A

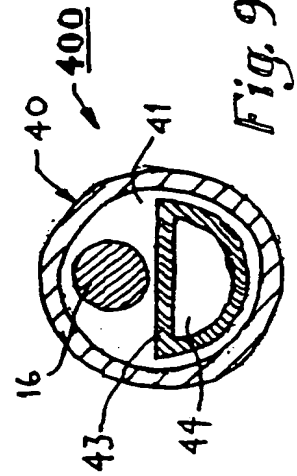


Fig. 9B

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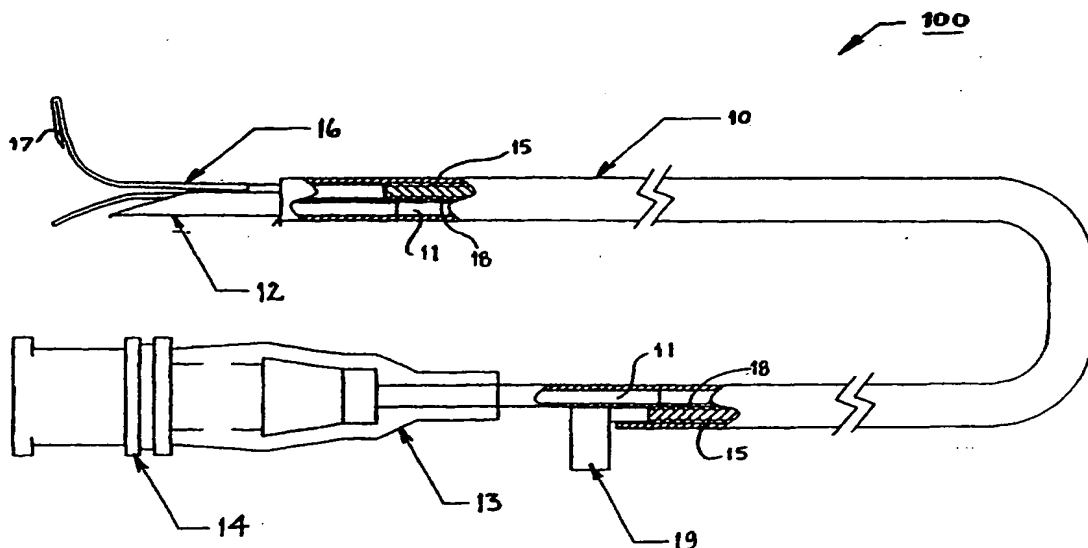
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- (74) Agent: **VAN BUSKIRK, Tedd, W.**; Milbank, Tweed, Hadley & McCloy LLP, 1 Chase Manhattan Plaza, New York, NY 10005-1413 (US).
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(57) Abstract: A device (100, 200, 300) and method for removing a fluid-filled object from a body cavity of a patient is provided. The device (100, 200, 300) includes a tube (10, 20, 30) and a grasper (16) slidably movable with respect to the tube (10, 20, 30). The device (100, 200, 300) also includes a needle (12) fixed to one end of the tube. In use, the device (100, 200, 300) is inserted into the body cavity, and the object is punctured with the needle. The object is grasped by the grasper (16), and the object and the device (100, 200, 300) are removed from the body cavity.

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INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 17/04

US CL : 606/148, 139, 110, 113, 126, 133, 151, 205, 206, 207.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/148, 139, 110, 113, 126, 133, 151, 205, 206, 207.

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ----- Y	US 5,817,111 A (RIZA) 06 OCTOBER 1998; Figs. 4-5, 8-10, 24-27).	1-6. ----- 7 and 10

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